



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Yash Sharma

Serial Number: 09/474,677

Art Unit: 1644

Filed: December 29, 1999

Examiner: Ronald B. Schwadron

Title: TREATMENT AND PREVENTION OF HIV AND OTHER VIRAL INFECTIONS

DECLARATION UNDER 37 C.F.R. 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

I, Yash Sharma, declare and state that:

1. I am a U.S. citizen.
2. I have a MSc. in biochemistry from the University of Delhi, India.
3. I have a Doctorate of Homeopathic Medicine from the University of Trivandrum, India.
4. I have a Ph.D. in biochemistry from the University of London, England.
5. I have extensive experience in the field of biological sciences and chemical sciences as is detailed in the curriculum vitae attached as Exhibit A.
6. After I filed for patent protection, I disclosed my efforts under a secrecy agreement to Dr. Diefenbach, Dr. Larry Dayton, Dr. McGowan, Dr. Turk and 18 other scientists at NIH.
7. Thereafter, further disclosures were made to Dr. Turk, who offered to validate my findings by independently testing the anti-viral activity of N-glycolylneuraminic acid

using NIH contractor's laboratory, Southern Research Institute, under a confidentiality agreement with the me. See Communications, attached as Exhibit B.

8. Dr. Turk is an agent of the NIH and due to confidentiality agreements is obligated to maintain the secrecy of my disclosures.
9. Similarly, Trevor O'Neil is a technician at a contractor lab who simply performed tests at my direction and using my advice to further validate my results.
10. Dr. Turk and Mr. O'Neil are not the inventors or co-inventors and, as such, are not named.
11. All statements made herein of my own knowledge are true and all statements made on information and belief are believed to be true; and further these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

11.5.04
Date

Yash Sharma
Yash Sharma

DR. YASH P. SHARMA
CURRICULUM VITAE

EDUCATION:

MSc. (with honors)- University of Delhi, India
MDH - Doctor of Homeopathic Medicine, University of Trivandrum, India
Ph.D. - University of London, England

PROFESSIONAL EXPERIENCE:

1997-Present President and CEO of Medicine and Applied Sciences, Virginia
1987-1991 Nuclear medicine studies, Holy Cross Hospital, Silver Spring, MD
1981-1987 Nuclear medicine studies, Montgomery General Hospital, Olney, MD
1974-1981 Nuclear medicine studies, George Washington University,
Washington, D.C.
1966-1974 Assistant Professor in Biochemistry, AIIMS New Delhi India
1965-1966 Research Scientist, University of Toronto, Canada.
1964-1965 Research Scientist, University of Strasbourg, France
1960-1964 Research Scientist, St. Mary's Medical School, University of
London, UK.

PROFESSIONAL AWARDS AND ASSOCIATIONS:

Nuclear Medicine Society-SNM
New York Academy of Science
American Association for the Advancement of Science
Institute of Science Technology, England-AIST
Institute of Medical Technology, England-AIMT
Royal Society of Health, England- FRSH
Royal Microscopic Society, England-FRMS
Indian Medical Association-FIMA

RESEARCH EXPERIENCE:

ENGLAND- Thyroid metabolism studies in rats, methylation of steroids,
efficacy of streptokinase in clot removal, metabolic studies of anabolic
steroids, and study of effect of ultrasonic waves on cat brain.
FRANCE AND GERMANY- Gastrointestinal absorption of fats and proteins in
dogs using C14 labeled compounds, and surgical procedures.
CANADA- Biochemical effects of physical fitness, exercise devises, measurement
of blood gases, pH, lactate levels, expired gases, and vital signs.
INDIA- Diabetic neuropathic studies, studies of effects of Gum gugal and other
hypolipidemic drugs in humans, performed histochemical and
immunohematology techniques, and taught clinical chemistry and coordinated
academic activities of paramedical students.
HARVARD UNIVERSITY, BOSTON- Performed retinal degeneration studies in
mice using biochemical and radiochemical procedures.

GEORGE WASHINGTON UNIVERSITY- Performed radio immunoassays, blood volume studies, TSH stimulation studies, thyroid uptake studies, B-12 deficiency studies, and nuclear medical imaging.

MONTGOMERY GENERAL HOSPITAL- Performed nuclear medical imaging, nuclear cardiac studies, radiolabeling, and preparation of radio pharmaceuticals for use in humans.

HOLY CROSS HOSPITAL- Nuclear medical imaging, and preparation and labeling of radio pharmaceuticals.

MEDICINE AND APPLIED SCIENCES INC. (MASI)- Prepared formulations of several diagnostic kits, reagents and immunochemicals for *in vitro* use including, protein coating, and enzyme stabilizing, blocking agents. Formulation of several antimicrobial and anti viral agents for topical use. Formulation of several anti viral agents for blood and blood products safety. Development of biosensors and drug delivery systems. Development of automated Elisa and blood grouping and typing machine. Advertising, marketing and sales of proprietary products and technologies worldwide, Development of anti –HIV therapeutics. Lectures, seminars and presentations related to proprietary products and technologies at universities, medical schools, international pharmaceutical companies, NIH, and FDA. Coordination of R&D activities at various research centers, analysis of data, compilation of research reports. Filing and writing patent applications. Managing the technologies, R&D, and business of the company. Scale up manufacturing and contract manufacturing of reagents and products.

PUBLICATIONS

Yash Sharma, Sharon Duvall, Barbara McGraw and Helen Ridgeway, An antiviral agent for general use in biological samples and tissue. American Clinical Laboratory, October 1990 pages 22-32.

Y. Sharma, B.D Rawal, G.N Vyas. Chemical approach for inactivation of cell free viruses in blood. Transfusion, October 1991, supplement 8S pages 48S.

B.D Rawal, Y.Sharma G.N Vyas. Chemical inactivation of cell free human immunodeficiency virus experimentally infected into whole blood. Blood, January 1992.

Y. Sharma, Owen Weislow, Robert Buckheit. Use of an antiviral antimicrobial agent in blood packs and tissue cultures. Blood Safety and Screening, October 1995.

Sharma, Y., Minarcik, J., Gill, P., Ricordi, C. Experience with a white cell extract from species immune to AIDS. Cell Transplant Society Third International Congress, Miami Beach October 2, 1996

Y. Sharma, J. Minarcik. Vectored drug delivery of Taxol to lungs. Research Report, Lawnwood Medical Center, March 4, 1999.

Y. Sharma, Chimp's Immunity factor NGNA for treatment and prevention of AIDS, Ramalingaswami Research Symposium, AIIMS New Delhi, Feb. 12, 2003.

Subject: re: HIV immunity factor in chimps-LUKOR sugar

Date: Wed, 17 Feb 1999 17:56:45 -0500

From: Steven Turk <STURK@mercury.niaid.nih.gov>

To: "ysharma@worldnet.att.net" <ysharma@worldnet.att.net>

CC: Steven Turk <STURK@mercury.niaid.nih.gov>, Carl Dieffenbach <CDieffenba@mercury.niaid.nih.gov>

Dear Dr. Sharma:

Thank you for the summary information on LUKOR which you provided to 12 NIH staff members on February 6. The majority of the individuals receiving your message are members of the Division of AIDS and are cognizant of your regular interactions with myself and Dr. Dieffenbach regarding your efforts to develop this product. Informational updates such as that which you provided as a matter of process are forwarded to the appropriate staff here for a follow-up response -- myself in this case. Since I'm already quite familiar with this topic and the material you provided, I have little in terms of new insight to offer at this time. The observation that humans may have contracted the HIV virus from chimpanzees was indeed interesting, but seems to offer little in furthering the development of this particular product. A "chimp factor" may indeed lessen the disease symptoms seen in chimps vs. humans after virus infection, but clearly, if the virus originated with chimps, it was actively replicating in chimps in the presence of this "factor" or could not have continued to be propagated as an infectious agent.

We hope you have been receiving useful advice from us for advancing your drug development plans for this material. Investigators such as yourself naturally carry the primary responsibility for developing and commercializing new therapies. The Division assists investigators when it can via well established grant mechanisms to provide funding and by selective use of our contract resources to address certain drug development issues. These latter resources unfortunately are limited and generally are devoted to development of well characterized, pure materials. You already have taken all the appropriate steps required in seeking our assistance. We have offered to work with you to initiate in vitro evaluation of the newly identified active component of LUKOR, but remain hesitant at this time to offer substantial assistance in the development of the homogenate as a therapeutic agent. Discussions about potential clinical trial assistance from the Division would be premature at this time without substantial documented evidence that FDA is likely to issue an IND for the study of this material. We know you have been making progress in this area and encourage you to continue your discussions with FDA.

Thank you again for the information you provided. We hope the planned in vitro evaluations the Division will be doing for you proceed well and look forward to hearing from you as your IND negotiations with FDA move forward.

Steven R. Turk, Ph.D.
Division of AIDS, NIAID, NIH
Tel (301) 435-3771 Fax (301) 402-3171
e-mail: st15m@nih.gov

-----Original Message-----

From: Yash Sharma [mailto:ysharma@worldnet.att.net]
Sent: Saturday, February 06, 1999 6:35 PM
To: bl17u@nih.gov; cdc; ch25v@nih.gov; cp22n@nih.gov; fb10c@nih.gov;
gfolkers@nih.gov; jk31e@nih.gov; jk38m@nih.gov; jm79q@nih.gov;
mm52s@nih.gov; ns18p@nih.gov; Picaboo32@aol.com; rh25v@nih.gov;

Subject: RE: [Fwd: [Fwd: NeuGc]]
Date: Thu, 11 Mar 1999 14:11:35 -0500
From: Steven Turk <STURK@niaid.nih.gov>
To: 'Yash Sharma' <ysharma@worldnet.att.net>
CC: Steven Turk <STURK@niaid.nih.gov>

Will do. Thanks.

-----Original Message-----

From: Yash Sharma [<mailto:ysharma@worldnet.att.net>]
Sent: Wednesday, March 10, 1999 8:48 PM
To: Steven Turk
Subject: [Fwd: [Fwd: NeuGc]]

Dear Dr. Turk:

Here is information on Lukor active molecule. you can buy it directly from Sigma for you testing and share the results with MAASI as agreed under our existing CDA.

Yash